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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/845,245

04/27/2001

Mark M. Wang

263/168

2862

34263

7590

05/13/2005

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EXAMINER

HANLEY, SUSAN MARIE

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 05/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/845,245

Applicant(s)

WANG ET AL.

Examiner

Susan Hanley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 44-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 44-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/20/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

The amendment and response filed 2/25/05 are acknowledged.

Claims 1-14 and 44-46 are pending.

Terminal Disclaimer

The terminal disclaimer filed on 2/25/05 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 6,744,038 and US 6,778,724 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Double Patenting

Claims 1-14 and 44-46 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-41 of U.S. Patent No. 6,815,664. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of the patent is a specie of the genus of the claims of the instant application. The corresponding provisional rejection was applied to 09/993,318 which has since issued at U.S. 6,815,644. The grounds of the rejection remain the same as those stated in the Office action of 8/24/04.

Applicant did not respond to this rejection in the response filed 2/5/05. Therefore, the rejection stands for the reasons of record.

Claims 1-14 and 44-46 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-83 of copending Application No. 10/243,611.

Applicant did not respond to this rejection in the response filed 2/5/05. Therefore, the rejection stands for the reasons of record.

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Claims 1-14 and 44-46 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/324,926.

Applicant did not respond to this rejection in the response filed 2/5/05. Therefore, the rejection stands for the reasons of record.

Claims 1-14 and 44-46 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-16 of copending Application No. 09/993,376 which has been allowed but has not yet issued.

Applicant did not respond to this rejection in the response filed 2/5/05. Therefore, the rejection stands for the reasons of record.

Claims 1-14 and 44-46 are provisionally stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 10/326,568.

Applicant did not respond to this rejection in the response filed 2/5/05. Therefore, the rejection stands for the reasons of record.

Claims 1-14 and 44-46 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 10/326,796.

Applicant did not respond to this rejection in the response filed 2/5/05. Therefore, the rejection stands for the reasons of record.

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Claims 1-14 and 44-46 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 10/427,748.

Applicant did not respond to this rejection in the response filed 2/5/05. Therefore, the rejection stands for the reasons of record.

The following are new grounds of rejection:

Claims 1-14 and 44-46 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 09/326,905. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of co-pending application is a specie of the genus of the claims of the instant application. The '905 claims are drawn to a method for detecting cellular differentiation based on how a plurality of cells responds to a moving optical gradient that can the displace the cells and analyzing the cells based on the results of the movements. These steps correspond to the method of the instant generic invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-14 and 44-46 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 09/325,601. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of co-pending application is a specie of the genus of the claims of the instant application. The '601 claims are drawn to a method for identifying activated T-cells from naïve T-cells based on how a sample of T-cells responds to a moving optical gradient that can the displace the cells and

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analyzing the cells based on the results of the movements. These steps correspond to the method of the instant generic invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-14 and 44-46 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-32 of U.S. Patent No. 6,784,420. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of the patent is a specie of the genus of the claims of the instant application. In '420, the claims are drawn to a method of separating cells based at least in part upon how the dielectric constant of the particles responds to an optical force gradient.

Claims 1-14 and 44-46 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 29-45 of copending Application No. 09/267,914. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of co-pending application is a specie of the genus of the claims of the instant application. The '914 claims are drawn to a method for characterizing a cell or particle based on how a cell moves through a flowing zone in response to an optical force gradient.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments with respect to claims 1-14 and 44-46 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 and 44-46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for characterizing a particle based on its response to having been contacted with an optical gradient field having a uniform, non-focused intensity pattern, does not reasonably provide enablement for characterizing a particle based on its response to having been illuminated with a non-trapping optical force. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are drawn to the characterization of a particle based on how it moves in response to interaction with a non-trapping optical force. The instant specification discloses that particles can be displaced by subjecting them to an optical gradient field that has a uniform and non-focused intensity pattern, as depicted in Fig. 11a-b. The instant specification defines optical tweezers, which are well known in the prior art as a trapping means, as "light having a highly focused beam to a point in space of sufficiently high intensity, typically with the gradient force being sufficiently strong to overcome the scattering force" (p. 17 and depicted in Fig. 11c). Therefore, the invention of the instant application appears to be based on a optical gradient field having a uniform, non-focused intensity pattern vs. a focused optical gradient field which is also known as optical tweezers. However, the scope of the term "non-trapping" is unclear. What other types of "non-trapping optical forces" are there besides that which is disclosed in the instant application? Neither the prior art nor the instant specification provide the skilled artisan with guidance to ascertain other kinds of non-trapping optical forces besides that which is disclosed in the instant specification.

It appears that the method of characterizing a particle based on non-trapping optical forces is based on a certain type of optical intensity pattern that is uniform that is not focused on a point, as is the case with optical

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tweezers. However, the instant specification does not disclose if this embodies the scope of the term “non-trapping optical force”. It would require the skilled artisan perform undue experimentation to determine what other optical non-trapping forces are encompassed by said term since neither the instant specification nor the prior art teach other types of non-trapping optical forces. The limited disclosure cannot be extrapolated by the skilled artisan to predict what other types of optical gradient fields could be or are ‘non-trapping’. Thus, claims 1-14 and 44-46 are not commensurate in scope with the enabling disclosure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 and 44-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected because the term “non-trapping” is vague and indefinite. The term “non-trapping” is not defined or characterized in the instant specification. The use of a negative limitation without a definition or characterization in the specification renders the term vague and indefinite because it is unclear what is an optical force that does not trap. Further, it is unclear what is not trapped.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 5-8, 11-14, 45 and 46 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Imasaka et al. (US 6,224,732).

Imasaka et al. disclose a method of irradiating particles in a flow cells with interfering light to form interference fringes in the flow path. This disclosure meets claims 1-2 because a light from an interference fringe is an optical gradient, as described in the instant specification on p. 11. The moving

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particles receive a braking force when they pass through the light. The force is proportional to the size and/or the refractive index of the particle. Smaller particles are less affected by the force and separate from the larger particles. The separation of particles is observed, thus meeting the limitations of claims 1, 7, 8, 11-14, which are based on the extent to which the particles move. The particles can be cells, viruses, microorganisms, DNA, RNA, dust and the like (col. 2, lines 45-63) which meets the limitations of claims 45-46. Imasaka et al. refer to the interference fringes as a light gradient and its interaction with the particle in the flow is called a force (col. 5, lines 49-62). The light of the gradient is scanned in a direction to cross the flow path of a linear pattern which meets the recitation of a moving optical gradient, as in claim 3. The scanning light can be adjusted according to its intensity, modulating or a filter element or the wavelength (col. 6, lines 28-40). Imasaka et al. teach that the particles can also be subjected to an electro-osmotic force, thus meeting claim 5 which is related to subjecting the particle to a second force.

Claims 1, 2, 4, 6-8, 11-14, 45 and 46 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Imasaka et al. (Anal. Chem. (1995) 87: 1763-5).

Imasaka et al. disclose a method of irradiating particles in a flow cell with an optical gradient force and a scattering force (p. 1784, col. 2, first paragraph). The moving particles receive a braking force when they pass through the light, as in claim 1, 2 and 4. The force is proportional to the size and/or the refractive index of the particle. Smaller particles are less affected by the force and separate from the larger particles. The separation of particles is measured, thus meeting the limitations of claims 1, 6-8, 11-14, which are based on the extent to which the particles move. The particles can be cells (p. 1763, left col.) which meets the limitations of claims 45-46.

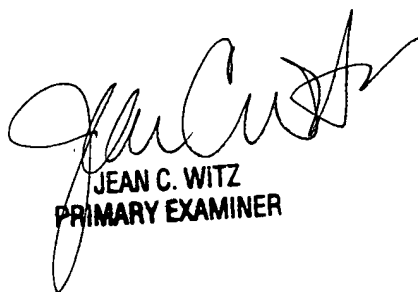
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan Hanley
Patent Examiner
AU 1651



JEAN C. WITZ
PRIMARY EXAMINER